# PSJ3

# Exhibit 465

HDMA
Healthcare Distribution Management Association

**DRAFT** **Not for External Circulation**

September __, 2011

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[ HYPERLINK "http://www.regulations.gov" ]

Drug Enforcement Administration
Attn: DEA Federal Register Representative/ ODL
8701 Morrissette Drive
Springfield, VA 22152

**Re: Controlled Substances and List I Chemical Registration and Reregistration Fees [FR Doc No: DEA-346P] 76 Fed. Reg. 39318 (July 6, 2011).**

Dear Docket Officer:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments on the Drug Enforcement Administration's (DEA) Federal Register notice: *Controlled Substances and List I Chemical Registration* [FR Doc No: DEA-346P] 76 Fed. Reg. 39318 (July 6, 2011).

HDMA is the national association representing primary healthcare distributors, the vital link in the healthcare system. Each business day, HDMA member companies ensure that more than nine million prescription medicines and healthcare products are safely delivered to more than 164,000 pharmacies, hospitals, nursing homes, physician offices, clinics and others nationwide. HDMA and its members work daily to provide value and contain costs, saving the nation's healthcare system an estimated $32 billion per year. For more information, visit [ HYPERLINK "http://www.HealthcareDistribution.org" ].

While HDMA understands and appreciates the importance of DEA's mission and the Agency's desire to be fiscally responsible, we believe that the continued registration fee increases, and the underlying programs they are being used to support, should undergo a very careful reassessment before the increase is finalized. In particular, we recommend that the Diverse Control Program (DCP) reassess the methodology used to select the fee increase, renew efforts to contain costs, and develop a clear measurement of effectiveness in preventing diversion so that any fee increase is more likely to result in our joint goals of reducing the risk of diversion and misuse.

As a result, HDMA requests that DEA take the following comments under consideration.

**1. Reassess the Fee Increase Methodology**

A key reason given for selecting the weighted-ratio method for determining a fee increase is related to the volume of drugs managed by each registrant category. With regard to the assertions that the larger the volume, the greater the fee increase because "*inspections, scheduled investigations and other control and monitoring costs are greatest...*" and because "*...there is an increased risk associated with the quantity of controlled substances and/or chemicals...*" in locations containing larger volumes of drugs,[1] HDMA offers the following comments.

[1] 76 FR 39326 col. 3.

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DCP reasons that because of the high volume/high risk associated with certain registrants, it is appropriate to assign to such high volume locations a greater share of the fee increase, hence the choice of the weighted-ratio method to determine the fee increase. HDMA is extremely concerned about the agency's characterization of relative risk because DEA has not placed into the administrative record information documenting that there are any greater risks for diversion *from the wholesale distributors' facility* than any other portion of the distribution chain.

More recent history indicates that diversion is occurring at the prescribing and dispensing level, with criminal elements concealing their activities in order to obtain access to excessive wholesale quantities.[2] The entire "Internet Distributor Initiative"[3] is premised on the fact that these prescribing and dispensing portions of the distribution chain are the sources at which controlled substances pass from legitimate to illicit use.

The DCP also cites additional responsibilities for administering several new statutes enacted since the last fee increase as further justification for the proposed increase. These include the Combat Methamphetamine Epidemic Act of 2005, the Methamphetamine Production Prevention Act of 2008, the Combat Methamphetamine Enhancement Act of 2010, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, and the Secure and Responsible Drug Disposal Act of 2010.

These new legislative responsibilities reflect the concerns among Congress and the public about the increase in the level of individual abuse and misuse as well as the sources of the products being abused and intentionally establish few, if any, new requirements directly related to wholesaler distribution storage, handling, and shipping practices.

Rather, other locations in the supply chain, while containing lower volumes of products, are appropriately highlighted for the additional control activity due to the increase in abuse associated with access to such drugs through these sources.

*Reviewers, we looked into the amounts of PSE products purchased from wholesalers vs. manufacturers. Anecdotally, CHPA indicates that it is true that large chain pharmacies, mass retailers and groceries generally buy direct from manufacturers (not wholesalers) but we did not find hard data readily available. Should we include this part below?*

HDMA also points out that anecdotal information strongly suggests that many, if not most, large chain drug stores, as well as mass merchandisers and grocery chain stores containing in-store pharmacies typically purchase relatively few products containing pseudoephedrine (PSE) from wholesale distributors. Further, the volume of products containing PSE sold by pharmacies which purchase direct from manufacturers is considerably greater than that of the relatively small, independent pharmacies. Although PSE products are not the only ones covered by the listed chemical handler registration requirements, they are certainly the products of greatest concern in the illicit manufacture of methamphetamine. HDMA still maintains that the theory that the greatest concern about diversion is linked to the largest volume storage/handling facilities has not been documented, but even if it were correct, pharmaceutical wholesale distributors are not likely to store and handle the kinds of volumes of PSE products that would justify giving them a higher fee increase under the weighted-ratio methodology.

Given the above, HDMA questions the selection of the weighted-ratio methodology for determining the fee increase. Because higher volume locations disproportionately bear the financial support for addressing the underlying reasons

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[2] For example, see the DEA press release on "Operation Pill Nation" at: [ HYPERLINK "http://www.justice.gov/dea/pubs/states/newsrel/2011/mia022411.html" ]

[3] *See* DEA Congressional Testimony provided by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; May 16, 2007.

for the fee increase, we recommend that DCP reevaluate its chosen method. Additional control of the products located at these high volume level locations will do little to stem the growth in abuse and misuse that DCP is charged with addressing.

In sum:

- If DEA needs to expend additional resources in inspection and monitoring, those efforts should be directed to portions of the distribution chain at which diversion actually occurs,
- Choice of a fee methodology should appropriately reflect the actual diversion risk,
- Should DEA eventually demonstrate that high volume product locations are at increased risk of diversion, the administrative record should be adjusted to adequately support the agency's assertions of this risk, and
- DCP should also place on the record information regarding the volumes of products of concern associated with each type of entity so that valid comparisons of the fee increase to the volume of products stored may be made during the public comment process.

## 2. Renew Efforts to Contain Costs Within the DCP

While most federal agencies and departments are facing across-the-board budget reductions for critical programs and services, DCP is essentially seeking an increase in its funding. Similar to DEA, most of these agencies and departments must simultaneously address increased responsibilities, reorganizations and implementation of new legislative initiatives. They have had to be innovative in their approaches towards fulfilling their statutory requirements and make tough decisions to ensure the most effective and efficient tools and resources are funded and the ineffective and inefficient tools and resources are eliminated.

Although HDMA supports DEA's efforts to date to improve efficiencies and identify cost savings measures, we question DCP's decision to raise registration fees at a time when cost reduction is the norm throughout most of the rest of the government and urge the DCP to renew efforts to evaluate the programs leading to the fee increases.

***Reviewers: After further exploration, we don't believe it is advisable to include the following charts. The Producer Price Index (PPI), would be a more appropriate measure. The PPI measures the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services. However, there is very little PPI data available to use for these comparisons, and what data does exist doesn't show the kind of striking comparison that would support our point (see chart 3 below). If we had data over a longer time frame, we think the comparison would illustrate our point, but such data are not available. Thus, DEA may call into question our credibility.***

**[ EMBED PowerPoint.Slide.12 ]**

## 3. The Fee Increase for Wholesale Distributors Should Consider their Substantially Greater Share of the Overall Costs for Preventing Diversion

Wholesale distributors are working in other, unseen ways, to support the DCP's efforts to prevent the illicit use of these legitimate pharmaceuticals. Distributors have been working closely with DEA to help prevent drug diversion, and we believe this effort on their part exceeds that of any other single element of the drug supply chain, particularly for enhancing and maintaining their suspicious order monitoring programs, under the Distributor Internet Initiative mentioned above. Specifically, these efforts are designed to help prevent diversion among DEA-registered customers with whom the wholesale distributors are doing business.

Under these programs, distributors have been scrutinizing customers, identifying ordering patterns and passing critical information to DEA. These programs can include (but are not limited to) everything from pre-screening processes for customers, reviewing customer orders, and training internal staff on how to spot potential problem customers and orders. Much valuable information has been obtained through these programs, and orders that might otherwise have reached destinations for which they are not intended have been stopped in their tracks. But there has been a significant investment, in some cases reaching or exceeding multi-millions of dollars, by distributors to build and maintain these programs.

This significant investment, being made by wholesales to support DEA's efforts, should be taken into consideration when developing and increasing registration fees and an adjustment for the fees for wholesale distributors should be instituted accordingly.

Moreover, under the current DEA registration process, a significant portion of wholesaler distributors must register twice, not just as distributors of control substances but also of listed chemicals (iodine). This means that:

- They must maintain information systems for tracking two different DEA registration numbers;
- Go through the paperwork required to renew two registrations each year;
- The same registrant **must pay two registration fees**, instead of only one and will receive a two-fold increase once the new fee is established; and
- **DEA will likewise have duplicative burdens**. For example, DEA must track the dual registration numbers and will sometimes unnecessarily perform multiple inspections of single locations that must register twice.

These facilities are working to control total health care costs through greater efficiencies in managing inventory, ordering, and shipping of these products, and the main reason that certain distributor warehouses stock both types of products is so that they are able to help provide better, and more streamlined, patient access to needed medications. Thus, we believe that paying doubled registration fees for any facility, much less those that are helping to control the costs by stocking both types of products, is neither fair nor equitable.

Finally, as noted in #1 above, HDMA understands that most PSE products are NOT purchased through wholesale distributors. Most of the PSE products sold in pharmacies are purchased by pharmacies directly from the manufacturer. Because wholesale distributors store fewer PSE products than other locations, the volume of products used as justification for their greater fee increase is less than it appears DEA has assumed. Consequently, the fee increase that is already disproportionate due to the suspicious order monitoring expenses and the dual registration requirement, is even greater because they tend to be "skipped over" in the supply chain for PSE products, and do not have the volume of products assumed to be the primary predictor of diversion.

At the least, HDMA strongly urges DEA to extend the waiver from the registration requirement for persons who distribute, import or export a product containing a List I chemical if that person is registered to distribute controlled substances. HDMA's preference is to extend the waiver, not only to make the fee increase reasonable, but to simplify the hidden costs associated with registration recordkeeping (including tracking the assigned DEA registration numbers) for both wholesale distributors and for DEA,

However, lowering the overall cost of the registration fees could be considered as an alternative. We believe that there are several options that DEA could explore, such as providing a discount for the second registration fee or providing a 50% discount to the entities if they only handle one type of listed chemical product that is not exempt under controlled substance registration. HDMA would welcome the opportunity to discuss this issue with DEA further, but significant steps in helping to ease the burden of these duplicative fees.

**4. When Establishing the Fee Increase, Recognize that Drug Supply Chain Participants Are Also Experiencing Licensure and Registration Fee Increases from the States**

In addition to DEA's registration fee increase, the enormous investment in the suspicious order monitoring programs, and the duplicative registrant fee for distributors of controlled substances and listed chemicals, wholesale distributors have also been subjected to significant rate increases for state registration fees. For example, the state of Maryland raised their registration fee in 2010 from $500 for registration and renewal fees to $1,750 for registration and renewal fees.[4] Additionally, certain states, such as the state of Maryland, also require distributors to register separately to distribute controlled substances, adding another registration fee to do business.

While some of these expenses may seem minor, taken together they have a very substantial impact on the distribution industry, which operates within a very small profit margin (1% in 2009).[5] Any reduction in reimbursement or any increase in expenses will be acutely felt and many of those paying the fees must also do so for multiple facilities, multiplying the impact accordingly.

Thus, we believe it is appropriate to assess the impact of state fee increases on DEA registrants when determining an appropriate registration fee.

**5. Assess the Success of DEA Programs Based on the Increased Fees**

Similar to the previous registration fee increases established in 2006, the preamble to the proposal contains an explanation of how DEA plans to use the additional registration fees collected. The explanation includes a description of DEA's activities that will be supported by the fees such as increases in the number of special agents and in investigation cycle. Although we are pleased to see the explanation, there is a notable lack of information regarding the anticipated outcomes and results of the additional fees.

For example, has DEA projected the increases in the number of illicit methamphetamine laboratories that will be identified based on the increases in agents that the funding will support? How many additional drug theft or diversion prosecutions can be anticipated with the increased resources? How will DEA track these kinds of results and show a correlation between increased the fees and the reductions in the illegal diversion, sale and use of these drug products?

HDMA recommends that DEA develop a system of metrics, accountability and reporting to project and assess direct results of the additional funds. This type of analytical mechanism should show a correlation between the additional fees and successful outcomes.

6. **Allow Adequate Time for Registrants to Budget for the Fee Increases**

To better ensure that any fee increase does not place additional strain on already tight budgets, HDMA recommends that DEA ensure that the fee increases are implemented with enough time for registrants to adequately plan. In order to pay for the increase, HDMA's members would need to "reprogram" funds that were to be used for other

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[4] [ HYPERLINK "http://dhmh.maryland.gov/pharmacyboard/whatsnew/NEW%20FEE%20INCREASES%20ARTICLE%20121509%20ADJ%20LGN.doc" ]: New Fee Increases Effective February 1, 2010.

[5] Net profit margin after taxes to net sales. Table 18. 2010-2011 HDMA Factbook. The Facts, Figures & Trends in Healthcare. 2010.

distribution activities, and therefore, to ensure the least disruption, would need adequate time to plan and allocate funds.

More specifically, HDMA recommends that DEA delay the fee increase effective date for at least six months after the final rule has been published. We believe that at least six months would allow distributors and other registrants adequate time to revise their budgets, and otherwise plan for the additional costs and requirements.

**Summary/Conclusion**

In closing, HDMA summarizes its key points as follows:

- Reassess the fee increase methodology in light of the type of legislation and abuse/misuse circumstances leading to the cost increases since the last fee increase,
- Renew efforts to contain costs within the DCP,
- The fee increase for wholesale distributors Should Consider their substantially greater share of the overall costs for preventing diversion,
- When establishing the fee increase, recognize that drug supply chain participants are also experiencing licensure and registration fee increases from the states,
- Assess the success of DEA programs based on the increased fees, and
- Allow adequate time for registrants to budget for the fee increases.

HDMA appreciates the opportunity to provide these comments. If you have any questions, please do not hesitate to contact me at 703-885-0240 or at [ PRIVATE HREF="mailto:aducca@hdmanet.org" MACROBUTTON HtmlResAnchor aducca@hdmanet.org]. Thank you.

Sincerely,

Anita T. Ducca

Anita T. Ducca
Vice President, Regulatory Affairs